NOV 0 7 2001

# ellman Surgitron 120 IEC
# 510 (k) Summary

K013255

**1. Submitter name and address:**

Frank Lin, Ph.D.
Director of R&D engineering
ellman international
1135 Railroad Avenue
Hewlett, New York 11557

**2. Device name and classification:**

2.1 Device Name: Surgitron 120 IEC (Also known as Surgitron 4.0 Dual RF)
2.2 Classification: Class 2 device, 21 CFR 878.4400

**3. Description of the device:**

The ellman Surgitron 120 IEC enhanced capability Electrosurgery Generator described herein is a compact source of high power RF energy to be employed for a variety of radiosurgery procedures. This action is achieved by front panel selection of waveforms and power level. All selection is effected through push buttons and lamps which give the operator feedback of status. Power level for each mode is indicated by front panel digital displays which also show the status of self-test and monitoring. This display is interlocked with the controls to prevent operation when FAIL is displayed. The final output power control is made through foot and/or hand switches. Both Monopolar and Bipolar electrodes are provided. It is designed to comply with international safety standards.

**4. The intended use/indication for use of the device:**

4.1 Cutting

Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage. Skin Incisions. Biopsy. Cysts. Abscesses. Tumors. Cosmetic Repairs. Development of Skin Flaps, SkinTags, Blepharoplasty,

4.2 Blended Cutting and Coagulation

Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, Skin Tags, Papilloma Keloids, Keratosis, Verrucae, Basal CellCarcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of Skin Flaps,

4.3 Hemostasis

Control of Bleeding, Epilation, Telangiectasia

4.4 Fulguration
Basal Cell Carcinoma, Papilloma, Cyst Destruction, Tumors, Verrucae, Hemostasis.

4.5 Bipolar
Pinpoint, Precise Coagulation, Pinpoint Hemostasis in any field (Wet or Dry), Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage.

**5. Identification to predicate devices**

5.1.Sugitron IEC II with general use indication K001253
5.2 ERBOTOM ICC 200 with general use indication K933157

**6. Summary of the technological characteristics of the new device in comparison to the predicate devices.**

Substantial equivalence
In Technological Characteristics comparison

| FEATURE | elman SURGITRON 120 IEC (New Application Device ) | elman SURGITRON IEC II WITH GENERAL USE INDICATION K001253 PREDICATE | ERBOTOM ICC200 WITH INDICATION K933157 PREDICATE |
|---|---|---|---|
| Indications For Use | Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treat, and turbinate shrinkage. Also, see page 5 for detail. | Same As New Device | Same As New Device |
| Design Specification | UL544 and IEC601-2-2 | Same As New Device | Same As New Device |
| Output Energy | 120 Watt | 100 Watt | 200 Watt |
| Output Waveform (s) | 4.0 MHz Sin-wave CW, Fully Rectified, Partially Rectified, and 1.7 MHz for Fulgurating Spark-Gap | Same As New Device | 350KHz Sine-Shaped and 1MHz Pulse-modulated |
| Standards Met | UL2601 and IEC 601-1 601-2-2, BS15724:2.2 | UL2601 and IEC 601-1 601-2-2, BS15724:2.2 | IEC 601-1 |
| Delivery system and configuration | Monopolar and Bipolar | Monopolar and Bipolar | Same As New Device |
| Biocompatibility Test | Electrodes identical to predicate device | Same As New Device | Same As New Device |
| Sterilization Method(s) | Refer to page 6, Note I | Same As New Device | Not Indicated |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Frank Lin
Director of Engineering
Research and Development Department
Ellman International, Inc.
1135 Railroad Avenue
Hewlett, New York 11557-2316

Re: K013255
Trade/Device Name: Surgitron 120 IEC
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 27, 2001
Received: September 28, 2001

Dear Mr. Lin:

This letter corrects our substantially equivalent letter of November 7, 2001 regarding the file number.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

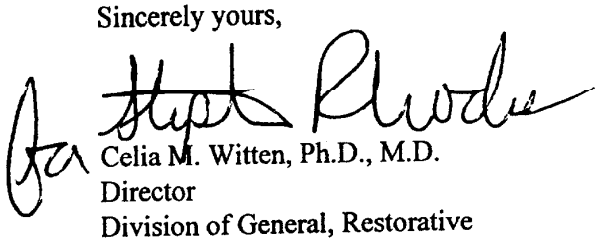
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

NOV 0 7 2001



**510(k) Number** (if known): K013255

**Device Name:** SURGITRON 120 IEC

**Indication For Use**: is idendical to the Surgitron as a preammendment device such as:

* Cutting
  Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, Skin Incisions, Biopsy, Cysts, Abscesses, Tumors, Cosmetic Repairs, Development of Skin Flaps, SkinTags, Blepharoplasty,

* Blended Cutting and Coagulation
  Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, Skin Tags, Papilloma Keloids, Keratosis, Verrucae, Basal CellCarcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of Skin Flaps,

* Hemostasis
  Control of Bleeding, Epilation, Telangiectasia

* Fulguration
  Basal Cell Carcinoma, Papilloma, Cyst Destruction, Tumors, Verrucae, Hemostasis.

* Bipolar
  Pinpoint, Precise Coagulation, Pinpoint Hemostasis in any field (Wet or Dry), Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The- Counter Use _____

(Optional Format 1-2-96)

510(k) Number K013255